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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION FOR U.S. LETTERS PATENT

Title:

VASCULAR PROSTHESIS

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VASCULAR PROSTHESIS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of application Serial No. 09/762,761, filed October 5, 2001, which is a 371 of International Application No. PCT/GB98/01418, filed May 15, 1998, claiming priority to United Kingdom patent application GB 9709967.5, filed May 17, 1997. This application expressly incorporates by reference the entirety of each of the above-mentioned applications as if fully set forth herein.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0002] Not applicable.

REFERENCE TO A COMPACT DISK APPENDIX

[0003] Not applicable.

BACKGROUND OF THE INVENTION

[0004] By-passes to save limbs may be required to have a relatively long length, such as the distance from the groin to below the knee, and may be required to attach to arteries that may be as small as 1 mm to 5 mm in diameter. Where patients have no other veins that can be used, as is often the case with patients having relevant serious conditions, the only positive alternative is to use prosthetic grafts of synthetic materials, for example flexible tubes of polytetrafluoroethylene (PTFE). Simple direct end connections or anastomosis of prosthetic graft tubes (usually run at an acute angle or more or less parallel with the artery and end cut at an angle) to side apertures in arteries, perhaps particularly arteries substantially less than 5mm in diameter, has unfortunately been followed by formation of fibrous intimal hyperplasia, which leads to serious blood flow reduction and even stoppage. The fibrous intimal hyperplasia occurs in regions within and around the graft connection, where there is little or no shear stress between the blood flow and the graft and arterial walls.

[0005] It is known to use a small piece of natural vein to make a short cuff known as the Miller cuff, that is joined by surgical stitching to and between the artery opening and the end of

the prosthetic graft tube. Improved success rates for indirect prosthesis-to-vein-to-artery connection, compared with direct prosthesis-to-artery, have involved reduced adverse effect from intimal hyperplasia. Contributory factors, for cuff type and other prosthesis types, have been considered and postulated as including reducing tendencies to turbulence of blood flow, and/or optimizing approximation to laminar blood flow, and/or for suppleness of the natural vein parts to aid absorption or cushioning blood pulsing. These factors have further been seen particularly as contributing to avoiding or minimizing occurrence of artery wall shear stress. However, fibrous intimal hyperplasia still occurs with the so called Miller cuff because regions of flow separation and low shear stress still occur within the cuff.

[0006] U.S. Pat. No. 5,156,619 discloses a vascular prosthesis comprising a tube of material other than autologous vascular tissue, the tube having an enlarged end formation for surgical connection direct to an opening formed in an artery, the formation having a heel and a toe at opposite ends of a first longer diameter parallel to the axis of the tube and a second shorter transverse diameter. WO 97/31591 discloses a flanged graft for end-to-side anastomosis grafting having an integral terminal flanged skirt or cuff, which facilitates an end-to-side anastomosis directly between an artery and the expanded flange bypass graft without need for an intervening venous collar or venous patch.

[0007] It has been proposed to provide a vascular prosthesis comprising a tube of synthetic material having an end formation for surgical connection directly to an opening formed in an artery, the end formation comprising an enlarged chamber serving to promote localized movement of blood having a non-laminar nature with a shear stress inducing relationship to the arterial wall. The term "non-laminar" as used herein is intended to define blood flow other than parallel to arterial walls and, in particular, includes localized laminar movement of blood having significant secondary components. The proposed enlarged chamber has a convex outer wall. Further experimentation, however, has revealed that this type of vascular prosthesis, while representing an improvement on the aforementioned Miller cuff may still not be ideal for certain applications.

[0008] Therefore, it is an object of the present invention is to provide an improved vascular prosthesis for use in vascular surgery.

BRIEF SUMMARY OF THE INVENTION

[0009] According to the present invention there is provided a vascular prosthesis comprising a tube of material other than autologous vascular tissue, said tube having an end formation for surgical connection direct to an opening formed in an artery, said formation comprising an enlarged chamber having a heel and a toe at opposite ends of a first longer diameter parallel to the axis of the tube and a second shorter transverse diameter, characterized in that a transition between the tube and the toe is outwardly initially convex before a final concave portion, whereby said enlarged chamber serves to promote localized movement of blood having a non-laminar nature with shear stress inducing relationship to receiving arterial wall.

[0010] The heel of the enlarged chamber is formed at one end of the longer diameter, and the transition between the tube and the heel is preferably generally concave. Transition between the tube and opposite ends of the shorter diameter is preferably outwardly convex. It is also preferable that the tube have a narrower portion prior to transition to the enlarged chamber. It is believed that such narrowing of the tube will increase blood velocity entering the enlarged chamber of the prosthesis and hence increase shear stress in that region. The grafts of the invention are preferably made of plastics material, especially polytetrafluoroethylene (PTFE).

[0011] The vascular prosthesis of the invention is intended to promote vertical blood flow in the region of its arterial connection in order to reduce or eliminate regions of low shear stress and regions of long residence times where blood elements can accumulate in the region of the graft connection. Separation of flowing blood from the inner wall of the tube near its enlarged chamber, and associated with non-laminar flow, is preferably such as to produce a swirling action that may include locally circulatory or re-circulatory movement of blood, further preferably in the nature of or including a vortex action. Such blood flow separation will usually occur directly at, as well as adjacent to, preferred acute angling of the prosthesis tube for its direct connection to the artery, which would be at least partially within the enlarged chamber. A preferred end chamber of the prosthesis tube of the invention is an enlargement which produces blood flow characteristics therein that result in an increase in wall shear stress.

[0012] Desired non-laminar blood flow promotion is preferably effective only in phases of cycles of blood-flow pulsing, which phases preferably alternate with other phases of more

laminar flow sufficient to assist flow of all blood into the artery away from that end of the prosthesis. The pulsed nature of normal blood flow involved successive time-spaced rises in pressure. Each pressure rise preferably causes both an initial relatively smooth or laminar blood flow in and out of the prosthesis-to-artery connection and a later transition into desired non-laminar blood movement. The preferred non-laminar vortex type movement preferably collapses before the next pressure rise.

[0013] These and other embodiments, features and advantages of the present invention will become more apparent to those skilled in the art when taken with reference to the following more detailed description of the invention in conjunction with the accompanying drawings that are first briefly described.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] FIG. 1 is a sectional line diagram useful for explaining problems arising from simple direct connection or anastomoses of a prosthetic graft tube of synthetic material to an opening made in an artery.

[0015] FIG.2 shows use of a veinous cuff interposed between a prosthetic graft tube and an artery.

[0016] FIG. 3 is a section through the graft of FIG. 2 showing typical blood flow therethrough.

[0017] FIG. 4 is a side view of a first prosthetic graft of the invention.

[0018] FIG. 5 is a rear view of the graft of FIG. 4.

[0019] FIG. 6 is a view from below of the graft of FIG. 4.

[0020] FIG. 7 is a perspective view of the graft of FIG. 4.

[0021] FIG. 8 shows the graft of FIGS. 4 to 7 connected to an artery.

[0022] FIG. 9 is a side view of a second prosthetic graft of the invention.

[0023] FIG. 10 is a rear view of the graft of FIG. 9.

[0024] FIG. 11 is a view from below of the graft of FIG. 9.

[0025] FIG. 12 is a perspective view of the graft of FIG. 9.

[0026] FIG. 13 shows the graft of FIGS. 9 to 12.

DETAILED DESCRIPTION OF THE INVENTION

[0027] The following detailed description should be read with reference to the drawings, in which like elements in different drawings are identically numbered. The drawings, which are not necessarily to scale, depict selected preferred embodiments and are not intended to limit the scope of the invention. The detailed description illustrates by way of example, not by way of limitation, the principles of the invention. This description will clearly enable one skilled in the art to make and use the invention, and describes several embodiments, adaptations, variations, alternatives and uses of the invention, including what is presently believed to be the best mode of carrying out the invention.

[0028] In the drawings, prior art devices are depicted in FIGS. 1-3. Referring first to FIG. 1, artery 12 has an opening made by an incision at 16. Prosthetic graft tube 10 of synthetic material (for which PTFE, most usually expanded PTFE (ePTFE), is widely used in practice) is run at an acute angle or more or less parallel to the artery 12. Tube 10 is indicated cut to an angled end 18 that is end to edge sewn into the opening 16. Unfortunately, there is a tendency for myointimal-hyperplasia to occur later in the receiving artery 12 (see indicated development of fibrous or scare-like tissue in the toe and heel positions 11 and 13, respectively), and also at plate position 15 opposite the opening 16. This development can seriously reduce the very blood flow that it is the object of the procedure to improve. Indeed, this condition all too often progresses to complete blockage of such blood flow. These problems are pronounced as the size of the receiving artery 12 decreases, which can be as small as 1 to 5 mm for the type of distal by-passes often needed, such as from the groin to beyond the knee as is frequently necessary to save a patient's lower leg.

[0029] FIGS. 2 and 3 illustrate the Miller cuff, aimed at reducing such problems by using a short length of another vein, usually from still usable parts of the saphenous vein that would be used in its entirety if serviceable. This short length of autologous vein, typically 2 to 3 mm in

diameter, is removed and opened along its length, then sutured first to an opening 36 of the artery 32 and end-to-end to itself at 39. The completed cuff 34 is trimmed and anastomoses completed at 38 to normally wider prosthetic graft tube 30. The graft tube 30 is typically made of PTFE and is at least 4 mm, preferably 6 mm if not more, in diameter. Improvement in terms of reducing development of intimal hyperplasia was originally, and has since consistently been, attributed to the autologous vein-to-artery junction. The suppleness of the veinous tissue may also have contributed to this improvement by assisting absorption of pressure pulsing and reducing shear wall stress in the receiving artery. Wall shear stress was assumed and reported as being the major causative factor in development of intimal hyperplasia. This procedure has become popular and has been the subject of considerable development, including similar use in interconnected small arteries.

[0030] Typical blood flow through the Miller cuff is shown in FIG. 3. A vortex 40 is formed to increase shear stress; however at opposite sides of the cuff, low shear stress regions 42, 44 develop where accumulation of deposits can form, resulting in intimal hyperplasia. Furthermore, where flow separates at the arterial wall opposite the cuff, a low shear stress region 46 also develops where intimal hyperplasia is possible.

[0031] Turning to FIGS. 4 to 8 of the accompanying drawings, a first vascular prosthetic graft 50 according to the invention is ideally made of polytetrafluoroethylene. The graft has a tubular part 52 of any desired length according to the length of the by-pass to be made using the graft and an enlargement 54 at one or both ends of the tube 52 (only one is shown). The enlargement 54 has an open end of a generally oval cross-section forming a heel 56 and a toe 58 at opposite ends of the larger diameter of the open end. There is a generally outwardly concave transition 60 between the tube 52 and the heel 56 and between the tube 52 and the toe 58 a firstly convex 62 and a final concave 64 transition. Sides 66 of the enlargement 54 at opposite ends of the shorter diameter of the open end are generally outwardly convex.

[0032] The plane of the open end of the enlargement 54 and of the tube 52 are generally parallel but it should be noted that prosthetic grafts having different separations thereof may be made for use in different situations. It should be further noted that prosthetic grafts having open ends of varying longer diameters may be produced. Furthermore, the degree of curvature either to the heel or the toe may be varied from graft to graft, in order to alter blood flow characteristics

through the graft connection. The prosthetic graft 50 is in practice connected to an artery by forming a slit in a side of an artery 67, opening out the slit and stitching the open end of the graft to the sides of the slit. It is to be noted that such connection of the graft causes the artery to have a concave underside opposite the graft as can be seen at 68 in FIG. 8 of the drawings. The length of the open end of the graft will probably be in the order of 14 to 36 mm and the width of the open end is unlikely to be less than 6 mm and probably not greater than 14 mm.

[0033] FIGS. 9 to 13 illustrate a variation on the prosthetic graft of the present embodiment. Like parts have been numbered similarly and only the main difference between them will now be described. In order to increase the velocity of blood flow through the graft connection to an artery, the tube 52 of the graft includes a narrower portion 70 prior to commencement of the enlargement.

[0034] The present invention has been described above in terms of certain preferred embodiments so that an understanding of the present invention can be conveyed. However, there are many alternative arrangements not specifically described herein but with which the present invention is applicable. Although specific features have been provided, the device of the present invention would equally be embodied by other configurations not specifically recited herein. The scope of the present invention should therefore not be limited by the embodiments illustrated, but rather it should be understood that the present invention has wide applicability with respect to vascular prostheses generally. All modifications, variations, or equivalent elements and implementations that are within the scope of the appended claims should therefore be considered within the scope of the invention.